UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,503	02/18/2004	Matthew F. Ogle	3126.03US02	2970

62274 7590 09/16/2010

DARDI & HERBERT, PLLC
Moore Lake Plaza, Suite 205
1250 East Moore Lake Drive
Fridley, MN 55432

EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
09/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,503	OGLE ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-35,37 and 47-57* is/are pending in the application.

4a) Of the above claim(s) *48 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21,24-26,28-35,37,47,54,55 and 57* is/are rejected.

7)☒ Claim(s) *22,23,27,49,50,52,53 and 56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/13/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 13, 2010 has been entered.

2. Applicant is advised that the Notice of Allowance mailed is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

3. Due to the filing of the request for continued examination and the reopening of the prosecution of this application, the claim amendments made in the notice of allowance on May 13, 2010 do not apply. Therefore, the status of the claims is as follows: Claims 20-35, 37, and 47-57 are pending and claims 48 and 51 are withdrawn from consideration.

Claim Objections

4. Claim 57 is objected to because of the following informalities: The recitation of "the surface capillary fibers comprises a polymer" appears to be in error as this recitation is already present in line 3 of claim 20.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 34, 35, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The non-porous surface being contoured to match a portion of a tissue structure within a patient is not disclosed or supported by the specification as originally filed. The specification as originally filed only discloses a medical device comprising a non-porous surface at least a portion of which is covered with surface capillary fibers. There is no disclosure of the non-porous surface being contoured to match a portion of a tissue structure within a patient.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 20, 25, 26, 47, 54, 55, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaughn et al ("Expanded Surface Area Fibers: A Means for Medical Product Enhancement").

Vaughn et al disclose a medical device comprising a plurality of surface capillary fibers associated with at least a portion of a surface of the device (as disclosed in line 14 of page 304 to line 20 of page 305 and line 21 of page 308 to line 28 of page 310). See Figure 2. In lines 14-19 of page 304, Vaughn et al disclose the fibers as being polymeric fibers. In lines 1-20 of page 305, Vaughn et al disclose that a quantity of bioactive agent is pre-loaded and in association with the surface capillary fibers such that the bioactive agent can elute in a controlled way from the fibers when the surface capillary fibers are in contact with a patient's body fluids or tissue. Furthermore, each of the surface capillary fibers comprises at least one capillary along its outer surface running along at least a portion of the length of the surface capillary fiber (lines 1-20 of page 305). In line 21 of page 308 to line 28 of page 310, Vaughn et al disclose that the medical device is a percutaneous device or an implantable device as the device may be any of those listed on page 310 such as absorbent burn pads, bandages with bacteria barriers, medicated wound dressings, surgical sponges, or transdermal wound

dressings. As to claim 25, see lines 1-20 of page 305 and Figure 2. As to claim 26, the device is configured for or considered to be capable of being for placement within a blood vessel without blocking flow through the vessel.

As to claim 47, Vaughn et al disclose using the device as disclosed above in applications as listed in Figure 10 where the use of the device in absorbent burn pads, bandages with bacteria barriers, medicated wound dressings, surgical sponges, or transdermal wound dressings would involve contacting a patient's body fluids or tissues with the plurality of surface capillary fibers. As to claims 54 and 55, the plurality of surface capillary fibers are associated with at least a portion of a surface of the device with an adhesive, mechanical binding, heat bonding, or chemical bonding (lines 1-20 of page 305). As to claim 57, see lines 1-20 of page 305.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaughn et al in view of Lorenz et al (U.S. Patent No. 5,156,601).

Vaughn et al disclose the device substantially as claimed. Even though Vaughn et al disclose the device as being products such as absorbent burn pads, bandages with bacteria barriers, medicated wound dressings, surgical sponges, or transdermal wound

dressings, Vaughn et al are silent on the specifics of the bioactive agent being an anti-microbial agent. Lorenz et al disclose a wound or burn dressing in which a bioactive agent such as an anti-microbial agent has been loaded or incorporated (lines 47-68 of column 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of Vaughn et al an anti-microbial agent as taught by Lorenz et al as both Vaughn et al and Lorenz et al disclose wound or burn dressings having a bio-active agent and Lorenz et al teach that it is well known to use an anti-microbial agent as the bioactive agent for wound or burn dressings.

11. Claims 28-31, 33-35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al (U.S. Patent No. 7,326,196).

As to claim 28, Olsen et al disclose a tubular medical device (12) having a tubular substrate having a wall with an interior surface (16) and an exterior surface (18) where a plurality of surface capillary fibers or filaments (36, 38) are associated with at least a portion of one of the surfaces with an adhesive, heat bonding, or chemical bonding as indicated in lines 13-30 of column 4 where the plurality of surface capillary fibers are associated with the exterior surface (18) by mechanical binding of the retainer (44) around the catheter (12) or attachment of the retainer over portions of the filaments by adhesive. The filaments (36, 38) are considered to be a plurality of fibers as the filaments are elongated thread-like structures and, therefore, are fibers (Figures 1-8 and line 43 of column 3 to line 12 of column 4). Furthermore, in lines 4-12 of column 4, Olsen et al disclose that the filaments or fibers have a cross sectional shape such as splined or star shape and, thus, each of the filaments or surface capillary fibers has at

least one capillary along its outer surface running along at least a portion of the length of the surface capillary fiber. Also, as disclosed in lines 31-66 of column 4, the surface capillary fibers or filaments (36, 38) form fluid pathways along an exterior surface of the fibers. Even though Olsen et al disclose the fibers or filaments comprising conventional medical grade suture, Olsen et al are silent on the specifics of the surface capillary fibers having lengths from about 500 microns to about 10 centimeters and having widths ranging from about 1 micron to about 200 microns. The instant disclosure describes these parameters as being merely preferable, and does not describe them as contributing any unexpected results to the device. As such, parameters such as lengths and widths of the fibers are considered to be matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to claims 29 and 30, the device (12) is a catheter (12) configured for placement within a vessel of a patient as the catheter is capable of being placed within a vessel of a patient and the catheter (12) is a microcatheter as it is capable of being placed within the narrow vessels of a patient. As to claim 31, the surface capillary fibers or filaments (36, 38) are associated with a bioactive agent (line 60 of column 4 to line 5 of column 5). As to claim 33, at least one of the surface capillary fibers is associated with at least a portion of the interior surface (16) as the fibers or filaments (36, 38) extend into the lumen (24) which is formed by or is a part of the interior surface (16).

As to claim 34, Olsen et al disclose a medical device (12) comprising a non-porous surface (18), at least a portion of which is covered with surface capillary fibers or

filaments (36, 38). The non-porous surface is contoured to match a portion of a tissue structure within a patient as the tubular sidewall (14) would match a blood vessel within a patient. Also, the medical device (12) of Olsen et al is capable of being delivered or implanted in the patient's body and at least a portion of the non-porous surface is considered to be contoured such that it matches a portion of the tissue structure . In lines 4-9 of column 4, Olsen et al disclose the filaments as being a fiber. Also, the filaments (36, 38) are considered to be a plurality of fibers as the filaments are elongated thread-like structures and, therefore, are fibers (Figures 1-8 and line 43 of column 3 to line 12 of column 4). Furthermore, in lines 4-12 of column 4, Olsen et al disclose that the filaments or fibers have a cross sectional shape such as splined or star shape and, thus, each of the filaments or surface capillary fibers has at least one capillary along its outer surface running along at least a portion of the length of the surface capillary fiber. Also, as disclosed in lines 31-66 of column 4, the surface capillary fibers or filaments (36, 38) form fluid pathways along an exterior surface of the fibers. In lines 60-64 of column 4, Olsen et al disclose that the medical device is a percutaneous device or an implantable device. As to claim 35, in lines 65-67 of column 2, Olsen et al disclose the non-porous surface comprising a polymer. As to claim 37, the surface capillary fibers or filaments (36, 38) are associated with a bioactive agent (line 60 of column 4 to line 5 of column 5).

12. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al in view of DiCarlo et al (U.S. Patent No. 6,929,626).

Olsen et al disclose the device and method substantially as claimed. Even

though Olsen et al disclose a bioactive agent, such as an anti-microbial agent, associated with the surface capillary fibers, Olsen et al are silent on the specifics of the bioactive agent comprising a thrombolytic agent such as heparin sulfate. In lines 35-50 of column 5, DiCarlo et al disclose a device having a textile material made up of fibers where a bioactive agent such as a thrombolytic agent or an anti-microbial agent is associated with the fibers in the same field of delivering a bioactive agent to a site in a patient's body. The thrombolytic agent may include heparin sulfate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide as the bioactive agent disclosed by Olsen et al a thrombolytic agent such as heparin sulfate as taught by DiCarlo et al as both Olsen et al and DiCarlo et al disclose a device with a bioactive agent, such as an anti-microbial agent, associated with the fibers of the device where the bioactive agent is to be delivered to a site in a patient's body and DiCarlo et al teach that it is well known to deliver a thrombolytic agent, such as heparin sulfate, to a treatment site by associating the thrombolytic agent with the fibers of the device.

Allowable Subject Matter

13. Claims 22, 23, 27, 49, 50, 52, 53, and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

14. Applicant's arguments with respect to claims 20, 21, 24-26, 47, 54, 55, and 57 have been considered but are moot in view of the new ground(s) of rejection.

15. Applicant's arguments with respect to claims 28-35 and 37 have been considered but are moot in view of the new ground(s) of rejection. As to Applicant's arguments in line 21 of page 9 to line 1 of page 10, the plurality of surface capillary fibers are associated with the exterior surface (18) with an adhesive as the surface capillary fibers are attached to the retainer (44) around the catheter (12) by adhesive (lines 13-30 of column 4). As to Applicant's arguments in lines 11-25 of page 10, the non-porous surface is contoured to match a portion of a tissue structure within a patient as the catheter or medical device (12) of Olsen et al is capable of being delivered or implanted in the patient's body and the flexibility of the non-porous surface of the device would allow at least a portion of the non-porous surface to be contoured to match a portion of the tissue structure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767